Sodium oxybate for narcolepsy with cataplexy

NHS Devon

Commissioning policy

The routine commissioning of sodium oxybate is accepted in Devon for the treatment of narcolepsy with cataplexy in adults aged 19 years and over as follows:

a) to allow continuation of treatment in individuals reaching 19 years old who had previously been successfully treated with sodium oxybate under the NHS England commissioning policy criteria

b) In patients aged 19 years and older who meet the following criteria

The Formulary Interface Group should include this in locally defined treatment recommendations.

Commissioning criteria:

Adults (aged 19 years and above) where attempts to control symptoms of narcolepsy with cataplexy have failed despite a trial of medication from each line of therapy for each symptom group for at least three months. Specifically:

1) Patients who present with narcolepsy with cataplexy according to International Classification of Sleep Disorders 3 (ICSD) criteria; **AND**
2) Adequately treated co-morbid sleep disorders (such as obstructive sleep apnoea and restless legs syndrome) as assessed by polysomnogram; **AND**
3) Are assessed as able to benefit from sodium oxybate by a properly constituted Multidisciplinary Team; **AND**
4) Either show incomplete response to, or have significant adverse effects as a result of, a trial of at least one medication from each line for each symptom group:

	Excessive daytime sleepiness	Cataplexy
First line:	Modafinil	Venlafaxine
Second line:	Methylphenidate, Dexamfetamine, Lisdexamfetamine, Atomoxetine	Clomipramine or SSRIs

Stopping criteria:

1) Serious adverse effects including signs of respiratory depression; **OR**
2) Show evidence of incomplete response at three months as assessed by clinical examination according to:
    a. For cataplexy: the severity and frequency criteria below; **AND**
    b. For narcolepsy: the Epworth or Paediatric sleepiness scale below.

At least one of the cataplexy scores (either severity or frequency) should improve after 3 months of treatment*

Severity of cataplexy	Frequency of cataplexy
1 = moderate weakness	0 = <1 episode per year
2 = can maintain posture with external support	1 = ≥1 attack per year
3 = loses posture and falls to the ground	2 = more than one attack per month
	3 = >1 attack per week
	4 = >1 per day

Improvements in narcolepsy should be monitored by using either the Epworth Sleepiness Scale or the Paediatric Sleepiness Scale.

*It is noted that patients with both a severity score of 1 and a frequency score of 0 or 1 are by definition unable to demonstrate the required improvement after 3 months, since their severity score cannot improve, and 3 months is inadequate to demonstrate the required reduction from baseline in frequency score. **These patients are therefore not suitable for a trial of sodium oxybate.**

Rationale for the decision

The NHS England commissioning policy indicates that sodium oxybate for the treatment of narcolepsy with cataplexy in children will be funded in specific circumstances.

There is currently no cure for narcolepsy with cataplexy, and most children treated under the NHS England criteria are likely to require lifelong treatment with sodium oxybate; the responsibility for funding this treatment passes to ICBs as the patient reaches 19 years old.

Meta-analyses of data from randomised controlled trials indicate that sodium oxybate offers an improvement in some of the major symptoms of narcolepsy with cataplexy (number of cataplexy attacks; daytime sleepiness, sleep attacks, nocturnal awakenings). These benefits are supported by additional data from open-label extension studies.

Given the NHS England commissioning policy, continuation of care for patients successfully treated in line with the above criteria is accepted, despite uncertainties about whether the cost of sodium oxybate represents value for money for the local

NHS. In the interests of equity, sodium oxybate for narcolepsy with cataplexy will also be funded in patients aged 19 years or older who meet the specific eligibility criteria laid out above.

The treatment pathway for excessive daytime sleepiness in this policy was updated in 2022 and differs from that described in the NHS England policy for children. This difference occurs as the pathway used in the Devon policy mirrors that described by the National Institute for Health and Care Excellence (NICE) in TA758 (Solriamfetol for excessive daytime sleepiness caused by narcolepsy) which is more representative of standard care provided to adults (19 years and above), as opposed to children.

Guidance notes on exceptionality

Where the circumstances of treatment for an individual patient do not meet the criteria described above exceptional funding can be sought. Individual cases will be reviewed by the appropriate panel of the ICB upon receipt of a completed application from the patient's GP, consultant or clinician. Applications cannot be considered from patients personally.

Date of publication:	Version:
26.09.2022	Policy agreed by NHS Devon ICB.